

REMARKS

Rejection of the claims under 35 USC §102

Claims 1-8 and 21-24 have been rejected under 35 U.S.C. 102(b) as being anticipated by EP 0335133 as evidenced by US 5,939,536. Applicants have clearly shown that phosphatidylcholines, such as those taught by EP 0335133, are lipids. Applicants have further illustrated the difference between  $\alpha$ -lyso phosphatidylcholine detergent taught by US 5,939,536, and the phosphatidylcholine lipid taught by EP 0335133. Nevertheless, The Action states that phosphatidylcholines are known detergents and that in literature, the 'use of phosphatidylcholine detergents' is known as evidenced by U.S. Patent 5,939,536, column 4 lines 24-30. However, the Examiner is incorrectly establishing basic scientific fact based on a single notation in an unreviewed patent application. Simple investigation of the references cited in this section of '536, would have revealed that:

- a) Ježak teach that phosphatidylcholine is a lipid used in forming a liposome (page 10522, 2<sup>nd</sup> column, 2<sup>nd</sup> and 3<sup>rd</sup> full paragraphs),
- b) Zhang et al. teach that phosphatidylcholine is soluble in chloroform (i.e. lipid; page 9773, 2<sup>nd</sup> column, first paragraph under "Experimental Procedures") and the used of phosphatidylcholine in the formation of phospholipid vesicles (page 9774, paragraph bridging columns 1 and 2).
- c) Dunn et al. described phosphatidylcholine as a lipid (see abstract) and  $\beta$ -Octyl glucoside (page 2547, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph) and CHAPS (page 2550, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph) as detergents, and
- d) Mundiña-Weilenmann teach the use of phosphatidylcholine in forming a liposome, not as a detergent (page 4068, 1<sup>st</sup> column, last paragraph; it is well known in the art that lipids form liposomes and detergents form micelles and disrupt liposomes).

Nowhere do any of these reference state or suggest that a phosphatidylcholine is a detergent. Applicants further provide with this letter, a Declaration under 37 C.F.R. 1.132, noting the differences between lipids and detergents and that the phosphatidylcholines of EP 0335133 are recognized in the art as lipids.

Claims 1-8 and 21-24 have been rejected under 35 U.S.C. 102(b) as being anticipated by US 5,858,398 as evidenced by US 3,578,591. Applicants have amended that claims to obviate the rejection. Specifically, Applicants have amended the claims 1 and 21 to recite "consisting

of” rather that consisting essentially of”. As stated in the previous reply, '398 teaches only a composition containing all of the following:

- 1) a pharmaceutical agent,
- 2) at least on water soluble phospholipid,
- 3) at least on lipid soluble phospholipid,
- 4) at least one non-ionic detergent having an HLB value of 15 or less,
- 5) at least one non-ionic detergent having an HLB value of 6 or less, and
- 6) at least one water soluble sterol.

In contrast, Applicants teach and claim a composition consisting essentially of:

- 1) a charge polypeptide and
- 2) a detergent of opposite charge.

The composition taught and claimed by the Applicants clearly provides a simpler composition for delivering a peptide to a cell.

Final Rejection:

Applicants previously filed a Request for Continued Examination and therefore believe they are entitled to two office actions. However, the Applicants have been give a final rejection on the first Action. Applicants further note that no justification has been provided for the final rejection on a first action. Applicants request that the Examiner withdraw the finality of the rejection.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1-8 and 21-24 should be allowable.

Respectfully submitted,

/Kirk Ekena/  
Kirk Ekena, Reg. No. 56,672  
Mirus Bio Corporation  
505 South Rosa Road  
Madison, WI 53719  
608-238-4400

I hereby certify that this correspondence is being transmitted to the USPTO on this date: <u>October 2, 2007</u> .  /Kirk Ekena/ Kirk Ekena
------------------------------------------------------------------------------------------------------------------------------------------------------